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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,365	04/10/2001	Avram Scheiner	279.280US1	7716

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EXAMINER	
OROPEZA, FRANCES P	

ART UNIT	PAPER NUMBER
3762	13

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,365	SCHEINER ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/14/03 (Amendment)* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10 & 12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The Applicant's amended claim 4 in the amendment filed 8/14/03 to overcome the rejection of record, hence the Yerich et al. rejection of record is withdrawn.

Claim Rejections - 35 USC § 102

2. Claims 1-12, 15-35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al. (US 5957861). Combs et al. disclose a device (10) with an impedance monitor for discerning edema through the evaluation of respiratory rate and/or impedance.

As to claims 2, 4, 15, 16, 17, 29 and 30, a thoracic impedance signal is detected using a thoracic signal detection module (17) (figure 1; col. 3 @ 16-25; col. 4 @ 33-34), that detects impedance associated with a fluid shift away form the thorax. Transthoracic impedance measurements give a good indication of the level of edema (abnormal accumulation of fluid) in patients (col. 1 @ 11-16). Edema provides a sign of failing heart circulation (col. 1 @ 28-30), and is manifest in pulmonary edema of increased water in the lungs (col. 2 @ 38-42). Edema is monitored to indicated patient health and to indicate the need for therapy modification (col. 2 @ 12-16 and 30-36; col. 3 @ 13-15; col. 4 @ 1-4; col. 5 @ 56-61; col. 9 @ 48-59; col. 12 @ 40-50; col. 13 @ 1-5; col. 13 @ 52- 58; col. 15 @ 24-27).

As to claims 2, 4, 15, 16, 17, 18, 29 and 30, therapy is provided based at least in part of the baseline portion of the detected thoracic impedance (col. 4 @ 1-4; col. 7 @ 13-33; col. 11 @ 48-53).

As to claim 3, a high frequency component of the thoracic impedance signal is attenuated (col. 5 @ 36-45; col. 6 @ 58 – col. 7 @ 5; col. 11 @ 37 – col. 12 @ 47; col. 13 @ 20-26; col. 13 @ 59-64).

As to claims 4, 9, 11 and 12, treatment with increased pacing is provided in response to an increase in the baseline portion of the thoracic impedance (col. 4 @ 1-4).

As to claims 5 and 11, motion is detected and therapy is provided based in part on the detected motion (col. 5 @ 36-45; col. 12 @ 1-16; col. 13 @ 20-26).

As to claims 6, 12 and 23, breathing is detected and therapy is provided based in part on the detected breathing (col. 5 @ 36-45; col. 12 @ 1-16; col. 13 @ 20-26; col. 13 @ 59-64).

As to claim 7, the rate of pacing therapy is adjusted based on the frequency components of the thoracic impedance relative to the fluid shift and breathing (col. 4 @ 1-4; col. 9 @ 48-59; col. 12 @ 40-50; col. 13 @ 1-5; col. 13 @ 59-64).

As to claim 8, therapy is increased to a fixed value or increased by a fixed value, or applied therapeutic energy is adjusted in response to increased impedance associated with the fluid shift (col. 4 @ 1-4; col. 12 @ 28-31; col. 15 @ 24-27).

As to claim 8, drugs are provided in response to increased impedance associated with the fluid shift (col. 4 @ 1-4; col. 5 @ 20-25; col. 8 @ 41-48).

As to claims 9 and 26, a thoracic fluid shift signal has a frequency cutoff value that is less than or equal to 0.01 – 0.5 Hz. (col. 7 @ 14-16).

As to claims 10 and 27, a thoracic fluid shift signal has a frequency cutoff value that is approximately 0.1 Hz. (col. 7 @ 14-16).

As to claims 15, 16, 17, 18, 29 and 30, multiple electrode configurations are disclosed including two, three and four electrode configurations associated with the thorax and/or heart (col. 3 @ 16-25; col. 4 @ 44-63; col. 5 @ 25-61; col. 9 @ 60-62).

As to claims 15, 16, 21-25 and 29, the impedance detection module includes an averager/ low pass filter to detect impedance shifts associated with, among other things, fluid shifts, breathing and the cardiac stroke portion (col. 7 @ 13-33; col. 12 @ 1-16; col. 13 @ 59-64).

As to claims 18, 29 and 30, a pacing therapy output module and a pacing stimuli rate controller are inherent elements of the pacing therapy system (col. 3 @ 38-51; col. 15 @ 24-27).

As to claim 19, the electrode can serve multiple purposes (col. 4 @ 48 – col. 5 @ 7).

As to claims 20 and 29, a thoracic (test) signal (detection) generator (16) is disclosed (figure 1; col. 3 @ 16-25; col. 4 @ 27-32).

As to claim 28, therapy is based on fluid shift and breathing (col. 14 @ 65 – col. 15 @ 2).

As to providing therapy based in part on the detected baseline impedance associated with a fluid shift away from the thorax, the following passages that teach providing therapy based in part on the detected baseline impedance associated with a fluid shift away from the thorax (col. 1 @ 11-16 and 28-30; col. 3 @ 13-15; col. 4 @ 1-4; col. 2 @ 12-16, 30-36 and 38-42; col. 5 @ 56-61; col. 7 @ 13-33; col. 9 @ 48-59; col. 11 @ 48-53; col. 12 @ 40-50; col. 13 @ 1-5; col. 13 @ 52- 58; col. 15 @ 24-27).

As to an averager/ lowpass filter that obtains a baseline portion of the thoracic signal associated with a fluid shift away from the thorax, all elements are believed to be addressed in the previous paragraph except for the averager/ low pass filter. The filter, read as the averager/ low pass filter, disclosed by Combs et al. is responsive to the fluid shift (col. 7 @ 4-50).

The Applicant's arguments filed 8/14/03 have been fully considered but they are not convincing.

The Applicant's asserts that Combs et al. relate to edema ("fluid shift toward the thorax") and not hypotension, ("fluid shift away from the thorax") as claimed by the Applicant. The Examiner disagrees. Edema is recognized to be fluid collection and hypotension is recognized to be low blood pressure. Low blood pressure is occasionally associated with a fluid shift in the body from the thorax/ lungs to the extremities and also associated in varying degrees with a failing heart circulation. The monitoring of edema, collection of fluid in the lungs and a shift of fluid collected in the lungs to the extremities, is significant to the instant invention as it can be an indicator of cardiac circulatory issues and impending/ existing low blood pressure issues.

In response to the applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., hypotension) is not recited in the rejected claim(s) 1-12 and 13-35. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

3. Claims 1-8, 15-20 and 30 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Pitts Crick et al. (US 6104949). Pitts Crick et al. disclose an implantable pulse generator system to diagnosis and treat congestive heart failure by sensing trans-thoracic impedance (42) as well as position (99) and relating these values to the baseline value (col. 2 @ 35 – col. 3 @ 9). The breathing is inherently detected based on the impedance measurement, indicating the degree of edema (col. 2 @ 29-40). The therapy involves increasing the heart rate by heart stimulation,

providing systemic drugs or both (col. 6 @ 11-30). A higher frequency component of the impedence signal is analyzed (col. 4 @ 40-47). The baseline is determined based on averages (col. 4 @ 30-34; col. 5 @ 36-51). Electrodes are associated with the leads and the canister; it is inherent that the electrodes may be designated as electrodes one, two, three or four or can use the same electrode for multiple purposes to sense or stimulate for pacing or impedance measurement depending on the area of the heart being measured (col. 3 @ 21-64).

As to fluid collection in the lungs,the thorax is a part of the body between the neck and abdomen, and the principal organs in the thoracic cavity are the heart and lungs. Fluid movement in and out of the lungs is deemed to read on fluid movement in and out of the thorax. Pitts Crick et al. explicitly disclose movement "of fluid in the thoracic cavity, especially in an around the lungs" (col. 4 @ 55-57) and "impedance changes caused by fluid changes in the trans-thoracic tissues, especially in the lungs" (col. 5 @ 34-39).

As to increasing the rate of pacing stimuli based at least in part on an increase in the baseline portion of the thoracic impedance, the medical device increases the rate of pacing stimuli based at least in part on an increase in the baseline portion of the thoracic impedance (col. 2 @ 51-54; col. 3 @ 16-20 and 32-36; col. 5 @ 53-58; col. 6 @ 8-30).

The Applicant's arguments filed 8/14/03 have been fully considered but they are not convincing.

The Applicant's asserts that Pitts Crick et al. relate to edema ("fluid shift toward the thorax") and not hypotension, ("fluid shift away from the thorax") as claimed by the Applicant. The Examiner disagrees. Edema is recognized to be fluid collection and hypotension is

recognized to be low blood pressure. Low blood pressure is occasionally associated with a fluid shift in the body from the thorax/ lungs to the extremities and also associated in varying degrees with a failing heart circulation. The monitoring of edema, collection of fluid in the lungs and a shift of fluid collected in the lungs to the extremities, is significant to the instant invention as it can be an indicator of cardiac circulatory issues and impending/ existing low blood pressure issues.

In response to the applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., hypotension) is not recited in the rejected claim(s) 1-12 and 13-35. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant appears to argue that Pitts Crick et al. teach treating edema/ CHF in response to a decrease in the baseline thoracic impedance (col. 5 @ 67). The Examiner disagrees. The Examiner reads the cited passage (col. 5 @ 63 – col. 6 @ 3) as monitoring fluctuations around the lowest impedance value associated with position change, to see if it the lowest value is a readily attained steady state, whether the lower level is continuing to lower over extended time/ monitoring periods, or whether the impedance returns to the baseline. Pitts Crick et al. teach treatment for edema is determined based on the maximum impedance (Zmax) and by comparing the baseline impedance (Zbase) to the average impedance (Za) (col. 6 @ 24-28; col. 6 @ 8-28).

4. Claims 1-8, 13-20 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Erlebacher et al. (US 6473640). Erlebacher et al. disclose an implanted device (1) for long-term detection and monitoring of congestive heart failure. A pacemaker generates signals and obtains a dual frequency signal that can measure venous impedance and pulmonary impedance, pulmonary impedance being indicative of pulmonary edema and the associate fluid shifts (col. 2 @ 37-54; col. 4 @ 7-18). Changes in the impedance measurements over time provide a baseline (col. 4 @ 19-30). The pacemaker rate is increased to reduce the congestion in the lungs; drug therapy can also be used (col. 5 @ 48-61). Electrodes are associated with the leads and the canister; the electrodes may be designated as electrodes one, two, three or four or can use the same electrode for multiple purposes to sense or stimulate for pacing or impedance measurement depending on the area of the heart being measured (col. 5 @ 51-55; col. 6 @ 20-51). An accelerometer may be included to determine the impact of activity and posture on the impedance measurement (col. 9 @ 46 – col. 10 @ 18).

As to fluid collection in the lungs, the thorax is a part of the body between the neck and abdomen, and the principal organs in the thoracic cavity are the heart and lungs, hence collection of fluid in the lungs is read as collection of fluid in the thorax. Erlebacher recognizes the correlation between impedance and tissue congestion read to be fluid collection (col. 2 @ 37-54).

The Applicant's arguments filed 8/14/03 have been fully considered but they are not convincing.

The Applicant's asserts that Erlebacher relates to edema ("fluid shift toward the thorax") and not hypotension, ("fluid shift away from the thorax") as claimed by the Applicant. The

Examiner disagrees. Edema is recognized to be fluid collection and hypotension is recognized to be low blood pressure. Low blood pressure is occasionally associated with a fluid shift in the body from the thorax/ lungs to the extremities and also associated in varying degrees with a failing heart circulation. The monitoring of edema, collection of fluid in the lungs and a shift of fluid collected in the lungs to the extremities, is significant to the instant invention as it can be an indicator of cardiac circulatory issues and impending/ existing low blood pressure issues.

In response to the applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., hypotension) is not recited in the rejected claim(s) 1-12 and 13-35. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheldon et al. (US 6044297). Sheldon et al. disclose a device that independently monitors blood pressure, detecting hypotension, and physical position/ posture and correlates these measurements with electrocardiogram data, enabling detection of hypotension associated with posture and hypotension not associated with posture, enabling pacing therapy as needed (abstract; col. 1 @ 7-16; col. 5 @ 33-45; col. 6 @ 4-12 and 53-65; col. 7 @ 17-59; col. 9 @ 10-13; col. 12 @ 6-9).

As to claim 14, therapy includes increasing the heart rate in response to hypotension (col. 7 @ 34-36).

The Applicant's arguments filed 8/14/03 have been fully considered but they are not convincing.

The Applicant asserts Sheldon et al. do not disclose detecting hypotension, detecting postural and non-postural hypotension, or treating postural and non-postural hypotension. The Examiner disagrees. Sheldon et al. disclose detecting hypotension (col. 6 @ 53-65; col. 7 @ 27-36), detecting postural (col. 7 @ 28) and non-postural (col. 7 @ 44) hypotension (col. 6 @ 53-65; col. 7 @ 27-59; col. 9 @ 10-13), and treating postural and non-postural hypotension (col. 5@ 42-46; col. 6 @ 53-65; col. 7 @ 27-59; col. 9 @ 10-13).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

9-14-03

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